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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,590,645 was filed on November 7, 1997, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, salmeterol xinafoate (Serevent® Diskus®), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act (FFDCA), this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156 if the product Serevent® Diskus® was reviewed and approved as a drug product and not as a medical device. Since regulatory review was performed under Section 505 of the FFDCA, the product Serevent® Diskus® must have been considered by FDA to be a drug product. Accordingly, in order for the patent to be eligible for patent term extension, the permission for commercial marketing or use of the active ingredient of the drug product, after the regulatory review period upon which the request for extension is based, must have been the first permitted use of the active ingredient under the provision of law under which regulatory review occurred. 35 U.S.C. § 156(a)(5). As stated in paragraph 4 of the application for patent term extension the active ingredient salmeterol xinafoate of the product Serevent® Diskus® was previously approved for commercial marketing or use. Accordingly, the patent appears ineligible for patent term extension.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Senior Legal Advisor/Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Shah R. Makujina
Glaxo Wellcome Inc.
Five Moore, Drive
Research Triangle Park, NC 27709